REMARKS

Applicants respectfully request reconsideration and reexamination in light of the foregoing amendments and following remarks.

1. Status of the Claims

As noted in the Office Action Summary, claims 1-35 stand pending. Claims 20-31 and 33-35 stand withdrawn. After entry of the above amendments, claims 1, 6, and 10 are amended and claim 7 has been cancelled. Thus, claims 1-6 and 8-35 are now currently pending. Claims 20-31 and 33-35 stand withdrawn.

The amendments are supported, for example, in at least the original claims. No prohibited new matter has been introduced. Applicants reserve the right to file a divisional or continuation on any subject matter cancelled by way of amendment.

2. Acknowledgement of Drawings

Applicants note with appreciation the acceptance of the drawings filed March 24, 2005.

3. Acknowledgement of Foreign Priority Documents

Applicants note with appreciation the acknowledgement of the claim for foreign priority under 35 U.S.C. § 119 (a)-(d) and receipt of the priority document from the International Bureau.

4. Acknowledgement of Information Disclosure Statements

Applicants note with appreciation the acknowledgement of the Information Disclosure Statements filed March 24, 2005 and July 21, 2006.

Applicants submitted a new IDS on December 8, 2008, and respectfully request consideration and acknowledgement of the same with the Office's next communication. Among the references, Applicants have supplied copies of the references listed in a Canadian Search Report, so they may be fully considered.

5. Election/Restrictions

The Office makes the restriction requirement final. Applicants request all the nonelected claims be timely rejoined as linked by a special technical feature. The special technical feature linking the claims makes a contribution over the prior art cited for the reasons provided below.

6. Double Patenting

Claims 1-12 and 32 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting purportedly as being unpatentable over claims 1-12 and 31 of copending Application No. 10/485,456 (hereafter "the '456 application") in view of Willatts et al., *Effect of Long-chain Polyunsaturated Fatty Acids in Infant Formula on Problem Solving at 10 Months of Age*, 352 The Lancet 688 (1998) [hereafter "*Willatts*"].

This rejection is traversed. The claims of the '456 application do not recite that the method "prevents decline of, improves, or enhances cognitive ability responses of a healthy person." The Office incorrectly relies on *Willatts* for that suggestion. *Willatts* does not teach that administration of arachidonic acid (AA) to healthy subjects results in increased cognitive ability responses.

Willatts teaches that administration of long-chain polyunsaturated fatty acids improves problem solving abilities of 10 month old infants. *See*, *e.g.*, p. 688. The specification defines cognitive abilities as the combination of processing speed and amount of resources allocated to process external stimuli. *See*, *e.g.*, p. 2, ll.1-5. External stimuli includes visual auditory, olfactory, gustatory, and somatosensory stimuli. *See*, *e.g.*, p. 1, ll. 33-35. Thus, the present specification specifically states that a composition shown to improve problem solving abilities does not necessarily improve, enhance or prevent the decline of cognitive ability responses. *See*, *e.g.*, p. 5, ll. 1-20. Therefore, *Willatts* cannot suggest a method to improve, enhance, or prevent the decline of cognitive ability responses in a healthy person. For at least these reasons, no *prima facie* case of obviousness has been adduced, and the rejection thus should be withdrawn.

Applicants further point out that the claims in the '456 application have not been allowed. It is foreseeable that the claims yet may be amended, which may render the claims unobvious for further reasons.

7. Rejection of the Claims Under 35 U.S.C. § 112, Second Paragraph

Claims 1-19 and 32 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

Applicants traverse. The Office alleges that the phrase "normal responses of cognitive abilities of a healthy person" is unclear. A claim complies with 35 U.S.C. § 112, second paragraph, when one of ordinary skill in the art understands what is claimed in light of the specification. *See Seattle Box Co. v. Industrial Crating & Packing Inc.*, 731 F.2d 818, 826, 221 U.S.P.Q. 568, 574 (Fed. Cir. 1984); MPEP § 2173.02. A word of degree is not indefinite where the specification provides a standard for measuring that degree. *See Id.*, MPEP § 2173.05(b). The phrase is amended to more clearly define the invention. The "cognitive ability responses of a healthy person" refers to normal functions including attention, memory, perception, language, calculation and the like, as opposed to impaired functions. *See, e.g.*, p. 2, ll. 7-13 of the specification. Therefore, the artisan would consider unimpaired cognitive abilities to be "cognitive ability responses of a healthy person." Further, one of ordinary skill in the art would have understood that "healthy" refers to cognitive ability health, because the invention is only concerned with health of cognitive abilities. For at least these reasons, the claims are definite, and the rejection should be withdrawn.

Claims 1-19 and 32 stand rejected under 35 U.S.C. § 112, second paragraph, allegedly as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Applicants traverse. The Office alleges that the artisan could interpret the claims such that the method results in two opposing outcomes. Claims 1, 6, and 10 are amended to clarify that the method is for "preventing decline of, improving, or enhancing cognitive ability responses of a healthy person." For at least these reasons, the claims are definite, and the rejection should be withdrawn.

8. Rejection of the Claims Under 35 U.S.C. § 102(b)

A. Alleged anticipation by *Willatts*

Claims 1, 13-19 and 32 stand rejected under 35 U.S.C. § 102(b) allegedly as being anticipated by *Willatts*.

Applicants traverse. The rejection is improper, because the cited art does not teach every element of the claims. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Accordingly, the rejections are improper and should be withdrawn.

Claim 1 requires arachidonic acid (AA) "in an amount sufficient to prevent decline of, improve, or enhance cognitive ability responses of a healthy person." *Willatts* fails to explicitly or implicitly disclose that limitation.

Willatts discloses long chain unsaturated fatty acid compositions having only 0.3% to 0.4% AA content. *See, e.g.*, p. 689, Table 1. Thus, *Willatts* teaches 0.3 g to 0.4 g of AA in 100 g of long-chain polyunsaturated fatty acids, which is not a sufficient amount "to prevent decline of, improve, or enhance cognitive ability responses of a healthy person." Major fatty acids of brain phospholipid membranes are AA and docosahexaenoic acid (DHA). Higher percentages of AA compared to other fatty acids are needed to "improve, enhance, and prevent the decline of cognitive ability responses of a healthy person." *See, e.g.*, p. 13, ll.9-14 of the specification. *Willatts* teaches smaller percentages of AA and DHA compared to other long-chain polyunsaturated fatty acids. Therefore, *Willatts* fails to disclose "an amount sufficient to prevent decline of, improve, or enhance cognitive ability responses of a healthy person."

Willatts allegedly teaches that administration of the particular long-chain polyunsaturated fatty acids improves problem solving abilities of infants. The Office attempts to correlate problem solving abilities and cognitive abilities. Problem solving is not included in the definition of cognitive abilities in the present application for the reasons presented above. Further, as explained above, improvements in problem solving do not correlate to improvements

in cognitive ability responses. Therefore, *Willatts* fails to disclose an improvement in "cognitive ability responses of a healthy person."

Dependent claims 13-19 and 32, which depend from claim 1, are also not anticipated for at least the same reasons as for claim 1. For at least these reasons, no *prima facie* case of anticipation has been adduced, and the rejection should be withdrawn.

B. Alleged anticipation by *Kiliaan*

Claims 1, 2, 6, 8 and 13-19 stand rejected under 35 U.S.C. § 102(b) allegedly as being anticipated by U.S. Publication No. 2002/0040058 to Kiliaan et al. (hereafter "*Kiliaan*").

Applicants traverse. Claim 1 requires arachidonic acid (AA) "in an amount sufficient to prevent decline of, improve, or enhance cognitive ability responses of a healthy person." *Kiliaan* fails to explicitly or implicitly disclose that limitation at least.

Kiliaan discloses a method for the prevention and/or treatment of vascular disorders and/or secondary disorders associated therewith, such as depression. *See, e.g.*, p. 2, para. 30. *Kiliaan* does not teach preventing the decline of, improving or enhancing cognitive ability responses of healthy person. *Kiliaan* requires a high ratio of DHA and eicosapentaenoic acid (EPA) to AA and dihomogammalinolenic acid (DHGLA) (p. 3, para. 38). Higher percentages of AA compared to other fatty acids are needed to minimize the effects of the other fatty acids and "improve, enhance, and prevent the decline of cognitive ability responses of a healthy person." *See, e.g.*, p. 13, ll.9-14 of the specification. Because *Kiliaan* provides high concentrations of fatty acids other than AA, *Kiliaan* does not provide the large percentage of AA needed to provide the improved cognitive ability responses. Therefore, for at least these reasons *Kiliaan* does not inherently teach AA "in an amount sufficient to prevent decline of, improve, or enhance cognitive ability responses of a healthy person."

Claim 6 requires "arachidonic acid content of triglycerides containing arachidonic acid as part or all of the constituent fatty acid is at least 10 wt% of the total fatty acid in the triglycerides." *Kiliaan* fails to disclose at least this aspect added from claim 7. Applicants note that the Office did not reject claim 7 under 35 U.S.C. § 102.

Dependent claims 2, 8, and 13-19, which depend from claims 1 and 6 respsectively, are also not anticipated for at least the same reasons as for claims 1 and 6. For at least these reasons, no *prima facie* case of anticipation has been adduced, and the rejection should be withdrawn.

9. Rejection of the Claims Under 35 U.S.C. § 103(a)

A. Alleged obviousness over *Willatts* in view of *Barclay*

Claims 1, 2, 6-9, 13-19 and 32 stand rejected under 35 U.S.C. § 103(a) allegedly as being unpatentable over *Willatts* in view of U.S. Pat. No. 5,583,019 to Barclay (hereafter "*Barclay*").

Applicants traverse. Claim 1 requires arachidonic acid (AA) "in an amount sufficient to prevent decline of, improve, or enhance cognitive ability resopnses of a healthy person." *Willatts* fails to explicitly or implicitly disclose that limitation in claim 1 for the reasons presented above. *Barclay* cannot be combined with *Willatts* to cure the deficiencies of *Willatts* for at least the following reasons.

The Office has established exemplary rationales that may support a conclusion of obviousness. *See* MPEP 2143. It appears the Office is basing the conclusion on the teaching, suggestion or motivation rationale. Yet, the Office provided no clear articulation for why it would be obvious to provide infant formula of *Willatts* with higher concentrations of AA or to substitute the infant formula of *Barclay* which contains higher concentrations of AA for the infant formula of *Willatts*. The Office must articulate reasons with rational underpinning to support legal conclusions of obviousness, not mere conclusory statements. *In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006).

Barclay fails to suggest or provide motivation to substitute the infant formula of *Barclay* for the formula of *Willatts*. Although *Barclay* teaches that AA is suitable for use as therapeutic and experimental agents in conjunction with a carrier for administration to infants, *Barclay* does not teach that compositions with higher concentrations of AA improve cognitive ability responses of healthy persons or even problem solving as addressed in *Willatts*. One of ordinary skill in the art would not find it obvious to substitute the infant formula of *Barclay* for the formula of *Willatts*. *Willatts* is concerned with finding the correct composition to improve problem solving, while *Barclay* is concerned with cellular metabolism and growth in infants.

See, e.g., col. 1, ll.26-30. Thus, there is no clear articulation let alone an expectation of success of why an amount of AA sufficient to "prevent decline of, improve, or enhance cognitive ability responses of a healthy person" is added to *Willatts*.

Further, the modification proposed by the Office would render *Willatts* unsatisfactory for its intended purpose. There is no suggestion or motivation to combine the references, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose. *See In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). *Willatts* discloses fatty acid compositions containing small percentages of AA compared to other long-chain unsaturated fatty acids (p. 689, Table 1). *Willatts* is concerned with improving problem solving in infants by the fatty acid composition described. As explained in *Willatts*, changes in the amounts of long-chain unsaturated fatty acids can have dramatic changes to problem solving (p. 688). Therefore, changing the fatty acid composition of *Willatts* to include a much larger concentration of AA would render *Willatts* unsatisfactory for its intended purpose of improving problem solving.

Regarding claim 6, there is no clear articulation for why the limitation "wherein the arachidonic acid content of triglycerides containing arachidonic acid as part or all of the constituent fatty acid is at least 10 wt% of the total fatty acid in the triglycerides" is obvious. The Office explains that *Barclay* describes the use of a triglyceride form of the long-chain unsaturated fatty acids to provide AA. However, no suggestion is articulated for why it is obvious to modify *Willatts* to use the triglyceride of *Barclay*. *Willatts* describes a fatty acid composition that improves problem solving containing a small percentage of AA. There is no motivation or expectation of success to modify *Willatts*, to use a completely different fatty acid composition having an AA concentration increased from 0.4 wt% to at least 10 wt%.

Dependent claims 2, 8-9, 13-19 and 32, which depend from claims 1 and 6 respectively, are also not obvious for at least the same reasons as for claims 1 and 6. For at least these reasons, no *prima facie* case of obviousness has been adduced, and the rejection should be withdrawn.

B. Alleged obviousness over *Willatts* and *Barclay* further in view of JP '891

Claims 1-19 and 32 stand rejected under §103(a) allegedly as being unpatentable over *Willatts* and *Barclay* as applied to claims 1, 2, 6-9, 13-19 and 32 above and further in view of JP 08-214891 (hereafter "JP '891").

Applicants traverse. *Willatts* and *Barclay* fail to teach the limitations in claims 1, 6, and 10 and cannot be combined for the reasons presented above. JP '891 cannot be combined with *Willatts* and *Barclay* to cure the deficiencies for the following reasons. JP '891 does not suggest adding AA in amounts that would provide for the limitation "of preventing decline of, improving, or enhancing cognitive ability responses of a healthy person" required in claim 1.

The Office has misconstrued JP '891, when stating that JP '891 teaches AA content of about 30%. The reference must be viewed for what it teaches as a whole. Paragraph 27 of JP '891 cited by the Office explains a particular example and discloses that the concentration of DHA is about 30%. The Office is correct that JP '891 teaches AA as an example of a long-chain unsaturated fatty acid, but only the examples of JP '891 disclose the amount used. In the examples, AA is present in amounts less than 3 wt%. *See, e.g.*, p. 7, Table 1. Therefore, it is not obvious to use AA in a triglyceride or fatty acid composition in an amount sufficient to "prevent decline of, improve, or enhance cognitive ability responses of a healthy person."

JP '891 further fails to suggest claim 6, because it does not suggest using triglycerides wherein the AA concentration is 10 wt% or more relative to all of the fatty acids. JP '891 also fails to teach "at least 5 mole percent of triglycerides with medium-chain fatty acids bound at the 1,3-positions and AA bound at the 2-position" as recited in claim 10. The claimed amounts would not have been obvious through optimization based on the cited references, because none of the cited references teach concentrations greater than 3 wt% AA. There is no motivation or expectation of success that higher amounts will provide any different result.

Dependent claims 2-5, 8-9, 11-19 and 32, which depend on claims 1, 6, and 10 respectively, are also not obvious for at least the same reasons as for claims 1, 6, and 10. For at least these reasons, no *prima facie* case of obviousness has been adduced, and the rejection should be withdrawn.

C. Alleged obviousness over *McGahon* in view of *Barclay*

Claims 1, 13-19 and 32 stand rejected under 35 U.S.C. § 103(a) allegedly as being unpatentable over McGahon et al. (hereafter "*McGahon*") in view of *Willatts*.

Applicants traverse. Claim 1 requires arachidonic acid (AA) "in an amount sufficient to prevent decline of, improve, or enhance cognitive ability responses of a healthy person." *McGahon* is silent to how much AA is present.

McGahon allegedly teaches AA enhances impaired performance in spatial learning tasks impairment of ability to sustain long-term potentiation (LTP). The Office attempts to correlate long-term potentiation and cognitive abilities. Long-term potentiation is not included in the definition of cognitive abilities in the present application for the reasons presented above. *McGahon* fails to disclose an improvement in "cognitive ability responses of a healthy person." Further, *McGahon* teaches "[t]he nature of the role of arachidonic acid in the genesis of LTP had not been elucidated." *See McGahon*, p. 14, 2nd col., lines 10-11. Although *McGahon* arguably may suggest that arachidonic acid relates to maintenance of LTP, *McGahon* fails to disclose a relationship between LTP and cognitive ability.

Willatts also fails to teach the method "of preventing decline of, improving, or enhancing cognitive ability responses of a healthy person" for the reasons presented above. Therefore, *Willatts* does not cure the deficiencies of *McGahon*.

Dependent claims 13-19 and 32, which depend from claim 1, are also not obvious for at least the same reasons as for claim 1. For at least these reasons, no *prima facie* case of obviousness has been adduced, and the rejection should be withdrawn.

D. Alleged obviousness over *McGahon* and *Willatts* further in view of JP '891

Claims 1-19 and 32 stand rejected under 35 U.S.C. § 103(a) allegedly as being unpatentable over *McGahon* and *Willatts* as applied to claims 1, 13-19 and 32 above and further in view of JP 08-214891.

Applicants traverse. *McGahon* and *Willatts* fail to teach the limitations in claims 1, 6, and 10 for the reasons presented above. JP '891 cannot be combined with *McGahon* and *Willatts* to remedy its deficiencies for the following reasons. JP '891 does not suggest adding AA in

amounts that "prevent decline of, improve, or enhance cognitive ability responses of a healthy person" as recited in claim 1.

Also, the Office has misconstrued JP '891, when stating that JP '891 teaches AA content of about 30%. The reference must be viewed for what it teaches as a whole. Paragraph 27 of JP '891 cited by the Office explains a particular example and discloses that the concentration of DHA is about 30%. The Office is correct that JP '891 teaches AA as an example of a long-chain unsaturated fatty acid, but only the examples of JP '891 disclose the amount used. In the examples, AA is present in amounts less than 3 wt%. *See, e.g.*, p. 7, Table 1. Therefore, it is not obvious to use AA in a triglyceride or fatty acid composition in an amount sufficient to "prevent decline of, improve, or enhance cognitive ability responses of a healthy person."

JP '891 further fails to suggest claim 6, because it does not suggest using triglycerides wherein the AA concentration is 10 wt% or more relative to all of the fatty acids. JP '891 also fails to teach "at least 5 mole percent of triglycerides with medium-chain fatty acids bound at the 1,3-positions and AA bound at the 2-position," as recited in claim 10. The claimed amounts would not have been obvious through optimization based on the cited references, because none of the cited references teach concentrations greater than 3 wt% AA. There is no motivation or expectation of success that higher amounts will provide any different result.

Dependent claims 2-5, 8-9, 11-19 and 32, which depend on claims 1, 6, and 10 respectively, are also not obvious for at least the same reasons as for claims 1, 6, and 10. For at least these reasons, no *prima facie* case of obviousness has been adduced, and the rejection should be withdrawn.

E. Alleged obviousness over *Kiliaan* in view of *Barclay*

Claims 1, 2, 6, 8, 9, and 13-19 stand rejected under 35 U.S.C. § 103(a) allegedly as being unpatentable over *Kiliaan* in view of *Barclay*.

Kiliaan fails to teach the limitations of claims 1 and 6 for the reasons presented above. *Barclay* cannot be combined with *Kiliaan* to remedy the deficiencies of *Kiliaan* for the following reasons.

Kiliaan discloses fatty acid compositions containing an excess of EPA over AA. *See, e.g.*, p. 3, para. 38). The elimination of EPA from the fatty acid composition of *Kiliaan* would render the *Kiliaan* unsatisfactory for its intended purpose. *Kiliaan* teaches a fatty acid

composition for the purpose of modulating inflammatory processes that may occur in vessel walls and cerebral tissue, to normalize plasma cholesterol levels, especially LDL-cholesterol levels and revert the atherosclerotic process and to increase fluidity of neuronal, erythrocyte and blood vessel membranes. *See, e.g.*, p. 3, para. 37. The composition must contain much higher concentrations of EPA than AA to perform those purposes. *See, e.g.*, p. 3, paras. 37 and 38. Therefore, *Kiliaan* teaches away from eliminating the EPA concentration and increasing the AA concentration in the fatty acid composition. Thus, the teachings of *Kiliaan* and *Barclay* cannot be combined because they teach away from each other.

Dependent claims 2, 8-9, and 13-19, which depend from claims 1 and 6 respectively, are also not obvious for at least the same reasons as for claims 1 and 6. For at least these reasons, no *prima facie* case of obviousness has been adduced, and the rejection should be withdrawn.

F. Alleged obviousness over *Kiliaan* in view of JP '891

Claims 1-19 stand rejected under 35 U.S.C. § 103(a) allegedly as being unpatentable over *Kiliaan* in view of JP '891.

Kiliaan fails to teach the limitations of claims 1, 6, and 10 for the reasons presented above. JP '891 cannot be combined with *Kiliaan* to remedy the deficiencies of *Kiliaan* for the following reasons. As explained above, JP '891 does not suggest to one of ordinary skill in the art that AA should be added in amount sufficient to "preventing decline of, improve, or enhance cognitive ability responses of a healthy person." JP '891 also fails to suggest triglycerides where the AA concentration is 10 wt% or more relative to all of the fatty acids or "at least 5 mole percent of triglycerides with medium-chain fatty acids bound at the 1,3-positions and AA bound at the 2-position," as recited in claims 6 and 10 respectively.

Dependent claims 2-5, 8-9, 11-19, and 32, which depend on claims 1, 6, and 10 respectively, are also not obvious for at least the same reasons as for claims 1, 6, and 10. For at least these reasons, no *prima facie* case of obviousness has been adduced, and the rejection should be withdrawn.

CONCLUSION

For at least the foregoing reasons, it is submitted that the method of preventing decline of, improving, and enhancing normal responses of a healthy person of independent claims 1, 6, and 10, and the claims depending therefrom, are patentably distinguishable over the applied documents. Accordingly, withdrawal of the rejections of record and allowance of this application are earnestly solicited.

Should the Examiner feel that any issues remain, it is requested that the undersigned by contacted so that any such issues may be adequately addressed and prosecution of the instant application expedited.

If there are any other fees due in connection with this filing, please charge the fees to our Deposit Account No. 50-0573. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,
DRINKER, BIDDLE & REATH LLP

Date: January 5, 2009

By: Brian Lathrop
Brian K. Lathrop, Ph.D., Esq.
Registration No. 43,740

1500 K Street, N.W., Suite 1100
Washington, D.C. 20005-1209
T: 202-842-8821
F: 202-842-8465